IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados,	)	
Plaintiff,	)	C.A. No. 05-586 (KAJ)
v.	)	
ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION,	)	
Defendants.	)	

BIOVAIL'S ANSWERING BRIEF IN OPPOSITION TO ANDRX'S MOTION TO CONSOLIDATE CIVIL ACTION NOS. 05-586 AND 05-730

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I. NATURE AND STAGE OF THE PROCEEDING

On December 21, 2005, Andrx filed the present motion to consolidate two patent infringement actions that Biovail brought against Andrx, Civil Action No. 05-586 filed on August 10, 2005, and Civil Action No. 05-730 filed on October 14, 2005. Biovail's response to Andrx's motion is set forth below.

II. SUMMARY OF THE ARGUMENT

Andrx ignores that Biovail has always been willing to consolidate the two infringement actions as long as (1) Andrx cooperated by timely providing the product samples that Biovail needs for its infringement analysis, and (2) Andrx agreed to modify the discovery schedule of the consolidated action the minimum amount necessary to reflect the fact that consolidation would introduce five additional Andrx products into this already complex litigation. Andrx has refused to address those issues. Instead it chose to needlessly rush to the Court to ask for relief that Biovail never opposed, without conducting any meaningful discussions as to how to fairly address the real world issues that will result from consolidation.

As to samples, Andrx has dragged its feet in producing requested samples of its copycat generic version of Biovail's 420 mg Cardizem LA product, which is the subject of the first infringement action. Andrx agreed on August 3, 2005 to produce various samples, yet to date it still has not provided all of the samples it agreed to produce six months ago. As to the five other products in the second infringement action, Andrx has produced samples of finished product, but has refused to produce, among other things, samples of the ingredients used in those products, notwithstanding that it agreed to produce these types of samples before the first action was ever filed.

As to the existing discovery schedule, that was based on the time required for discovery and a trial concerning only one product, namely, Andrx's generic version of Biovail's 420 mg Cardizem LA product. The second infringement action adds five additional products, namely, Andrx's generic versions of Biovail's 120, 180, 240, 300, and 360 mg Cardizem LA products. Thus, consolidation means that Biovail needs to review and analyze documents for five additional, different products. Depending on what those documents and other materials show, Biovail may have a great deal of additional work to do to prepare for its initial round of expert reports, which will now have to account for six products instead of one. Therefore, Biovail believes consolidation should only occur with a corresponding modest adjustment to the schedule. Assuming that Andrx cooperates by producing all the requested samples immediately, Biovail respectfully submits that, as reflected at Exhibit A, a brief three-month extension of the existing case schedule is warranted.

III. STATEMENT OF THE FACTS

A. The Infringement Actions

On June 22, 2005, Andrx sent Biovail a Paragraph IV Certification Notice ("Notice letter") in which Andrx represented that it had filed with the Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") seeking permission to make a generic version of Biovail's 420 mg Cardizem LA product. On July 19, 2005, Biovail requested information regarding Andrx's proposed product, and on August 3, 2005, Andrx agreed to provide that information, including samples of its proposed product, and samples of each of the individual ingredients that Andrx uses to manufacture its proposed 420 mg generic product. (1/6/06 Declaration of Preston K. Ratliff II ("Ratliff Decl."), Exhs. 1-2.) On August 10, 2005, Biovail brought suit against Andrx for infringement of U.S. Patent No. 5,529,791 (the

"'791 patent") (Civil Action No. 05-586). After several follow-up letters, finally on October 4, 2005, Andrx made a partial production of the requested samples. (Ratliff Decl., Exhs. 3-7.) However, some of those samples were damaged, and to date Andrx has not provided acceptable alternative samples. (Ratliff Decl., Exh. 8.)

On August 30, 2005, Andrx sent Biovail a second Notice letter in which Andrx represented that it had filed with the FDA a submission seeking permission to make five additional products, *i.e.*, 120, 180, 240, 300, and 360 mg generic versions of Cardizem LA. On October 14, 2005, Biovail brought suit against Andrx for infringement (Civil Action No. 05-730).

B. The Parties' Communications Regarding Consolidation

On November 29, 2005, ***Biovail*** first proposed that the parties agree to consolidating the two infringement actions. In addition, Biovail put Andrx on notice that an adjustment in the schedule of the consolidated case would be required if Andrx did not provide all of the samples that had been requested (Ratliff Decl., Exh. 9):[1]

Note that at this point, Biovail does not necessarily agree that the two cases can be consolidated under the existing schedule. Certainly, if Andrx does not agree to provide discovery on all of its proposed strengths, including samples, by December 30, 2005, Biovail

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[1] The '791 patent claims require that certain ingredients or components of Andrx's products not only just be present in the formulation, but also be in "admixture," which will be argued by Andrx to additionally require that these components be found in its drug product in some relationship to one another. After Biovail reviews Andrx's discovery materials with its experts, Biovail may very well decide to do some physical testing on Andrx's product(s), and/or components thereof, to buttress its infringement proofs on these claims.

does not believe it will be possible to consolidate the cases without an appropriate extension of the schedule.

On December 6, 2005, Andrx responded by threatening to seek Court intervention if Biovail did not agree to consolidate the cases under the schedule for the first infringement action. (Ratliff Decl., Exh. 10.) On December 7, 2005, Biovail reiterated that the circumstances under which it would agree to consolidation depended on whether Andrx timely produced (*i.e.*, by the December 30, 2005 due date) the documents and samples that Biovail requested -- for all six Andrx products. (Ratliff Decl., Exh. 11.) Biovail received no further correspondence from Andrx regarding consolidation, and on December 21, 2005, without ever even conferring with Biovail to attempt to resolve these relatively minor issues, Andrx filed the present motion to consolidate.

IV. ARGUMENT

A. Andrx Refuses To Provide Critical Discovery Regarding All Strengths Of Its Proposed Products

On two occasions, Biovail told Andrx it was willing to consolidate the two infringement actions if Andrx timely provided the discovery that Biovail requested. (Ratliff Decl., Exh. 9 and 11.) However, contrary to Andrx's motion papers, it still has not timely produced all of the samples and information relating to its products that Biovail requested.

For example, on August 3, 2005, Andrx agreed to provide samples of its 420 mg product, as well as, samples of each of the individual ingredients that Andrx uses to manufacture its proposed 420 mg product. (Ratliff Decl., Exh. 2.) Despite Biovail's several letters requesting the samples, Andrx did not provide any samples to Biovail until October 4, 2005, and some of those samples were damaged. (Ratliff Decl., Exh. 7.) On October 7, 2005, Biovail requested the missing samples, replacement samples, and confirmation that the damaged samples did not have

any effect on the other samples. (Ratliff Decl., Exh. 8.) Despite several attempts to obtain acceptable samples, to date Andrx has yet to provide all of the requested samples in satisfactory condition.

In addition, Biovail repeatedly requested that Andrx provide samples of each ingredient used in each of its dosage strengths.[2] (Ratliff Decl., Exhs. 12, 9, 13, and 14.) Andrx has not provided those samples, and has failed to say when it would provide the requested samples. Indeed, in its December 29, 2005 letter, Andrx expressly refused to provide all of the samples, and for the first time indicated -- without any explanation -- that one or more of the samples of ingredients requested incredibly do not exist (even though somehow finished tablets incorporating those ingredients do exist). (Ratliff Decl., Exh. 15.)[3] On January 6, 2006, Biovail requested once again that Andrx produce the samples it is entitled to, or provide an explanation why the samples no longer exist. (Ratliff Decl., Exh. 17.)

To consolidate the two actions on the existing schedule without any commitment from Andrx as to when it will produce the requested samples of Andrx's products would be

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[2] To determine whether certain components are in "admixture" as required by the '791 patent claims, it may become desirable to do physical tests on the finished tablets to ascertain the physical relationship between certain components of the product within the tablet matrix. Having separate samples of each ingredient before it is combined into the tablet matrix may aid that difficult and complicated chemical analysis.

[3] Perhaps this is because the FDA placed Andrx in Official Action Indicated status, suspending any further approval of Andrx's ANDAs, including apparently the ANDA and amended ANDA subject to these infringement actions. (Ratliff Decl., Exh. 16.) The FDA has provided no guidance as to when it will allow approval of any Andrx ANDA, and to date there has been no announcement that the FDA has removed the suspension. Thus, because a tentative approval date of Andrx's proposed products is speculative at best, any allegation by Andrx that there is any urgency to these infringement actions is tenuous.

prejudicial to Biovail -- assuming it were even possible to litigate a six product case in the time that had been allocated to a one product case.

B. The Existing Case Schedule Does Not Account For The Size Of The Proposed Consolidated Action

Andrx's unsupported assertion that the factual issues "do not differ in any material way" between the various dosage strengths is misleading and misplaced.[4] Biovail's second infringement action is directed to five different products.[5] Although Biovail is just beginning to review documents regarding those different products, it appears that they differ in certain respects. Andrx, in fact, has not represented (nor can it) that the five additional products are identical in every way to the 420 mg Cardizem LA product, which is the subject of the first infringement action. Thus, Biovail must now review and analyze the over 100,000 pages of documents that Andrx has recently produced to determine the relevant similarities and differences for each product. If the products differ in any material respect, follow-up fact discovery, and then expert discovery may need to be individually tailored to each product.

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[4] Andrx's assertion that there are "common facts" because Biovail mentions its own New Drug Application for Cardizem LA in both Complaints is a red herring. The infringement issues involve Andrx's products -- not Biovail's.

[5] Andrx's assertion that the second infringement action was filed for delay is specious. Andrx cites no authority requiring Biovail to file an amended complaint. The second action was based on Andrx's second Notice letter and the five new products identified in that letter, and was filed well after the initial litigation commenced. Had Andrx been truly interested in expediting this litigation, it should have submitted a single submission to the FDA at the outset, seeking approval of all six product strengths. Whatever caused Andrx to delay the submission for its additional five product strengths cannot be blamed on Biovail.

Biovail's expert reports regarding infringement are due on May 16, 2006, just a little over four months from now. At the time the existing schedule was entered only one product was at issue, and the schedule did not take into account discovery of, and assembling infringement proofs for, Andrx's five additional products. Thus, should the two actions be consolidated, Biovail respectfully requests that the Court grant a modest, three-month extension to the current schedule as shown at Exhibit A to take into account the substantial increase in scope of the litigation.

V. CONCLUSION

For all of the reasons above, Biovail respectfully requests that if the Court consolidates Civil Action Nos. 05-586 and 05-730, it also adopt Biovail's proposed schedule at Exhibit A to allow adequate time for fact and expert discovery regarding the six Andrx products that would be addressed at trial.

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January 6, 2006

CERTIFICATE OF SERVICE

I, Melissa Stone Myers, hereby certify that on January 6, 2006, I caused to be electronically filed **BIOVAIL'S ANSWERING BRIEF IN OPPOSITION TO ANDRX'S MOTION TO CONSOLIDATE CIVIL ACTION NOS. 05-586 AND 05-730** with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

William J. Cattie, III
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and that I caused copies to be served upon the following in the manner indicated:

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